In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 23-1926V UNPUBLISHED

KATHERINE M. HELTON,

Petitioner.

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 26, 2024

Bijan Esfandiari, Wisner Baum LLP, Los Angeles, CA, for Petitioner.

Julia M. Collison, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION¹

On October 31, 2023, Katherine Helton filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa—10 through 34 (the "Vaccine Act"). Petitioner alleges that she suffered various injuries from human papillomavirus ("HPV") vaccinations she received on May 3, 2016, and June 21, 2018. ECF No. 1 at 2.

Because the petition was untimely filed, and Petitioner has failed to establish a basis for equitable tolling, Respondent's motion to dismiss is **GRANTED** and this case is **DISMISSED**.

Relevant Factual Background

At appointments accompanied by her mother, Petitioner received the first HPV vaccination on May 3, 2016, when she was fifteen years old, and the second HPV vaccination on June 21, 2018, when she was seventeen years old. Exhibit 18 at 31-37 and 82-87. The contemporaneous medical records for each vaccination appointment state that "[c]ounseling performed on side effects, risks and benefits of immunization per

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

component. Consent given" and "[a]ppropriate CDC [Vaccine Information Statement (VIS)] given for each vaccine given." *Id.*

Within seven days of the first HPV vaccination in May 2016, Petitioner stated she began having seizures and developed other symptoms. ECF No. 1 ¶ 5. Over the next few years, Petitioner was diagnosed with various issues, including major depressive disorder, anxiety disorder, panic attacks, eating disorder, syncope, chronic constipation, dissociative seizures, chronic ovarian cysts, postural orthostatic tachycardia syndrome (POTS), gastroparesis, chronic urinary tract infections, cholecystectomy, hematochezia, attention-deficit/hyperactivity disorder, mononucleosis, and possible left atrial enlargement. *Id.* ¶¶ 7-17.

Petitioner alleged the preceding medical history in the petition. Facially, Petitioner's claim herein was filed over *five* after her last HPV dose, which was administered in June 2018, and over *seven* years from the time she began manifesting symptoms in 2016. But Petitioner maintains her delay is excusable. Petitioner stated at the time these vaccinations occurred, no one discussed the possible adverse side effects of the HPV vaccine, no Vaccine Information Statement (VIS) was provided, and no information was relayed about the Vaccine Program. Exhibit 12 ¶ 4. Petitioner stated that she only learned about the Vaccine Program in April 2023. *Id.* ¶ 5. Although Petitioner's mother accompanied her to both vaccination appointments, Petitioner did not submit an affidavit from her mother about whether any counseling or information was provided about the HPV vaccine or the Vaccine Program.

Relevant Procedural History

On November 7, 2023, Respondent filed a motion to dismiss arguing that the claim had been filed outside the Vaccine Act's 36-month statute of limitations, Sec. 16(a)(2). ECF No. 7. Respondent maintained that Petitioner had not diligently pursued her rights before filing a vaccine claim in 2023. Respondent also disputed the veracity of contentions about the manufacturer's conduct, and whether it could in any event constitute an extraordinary circumstance that would serve as a basis for tolling the statute of limitations.

On December 12, 2023, Petitioner filed a response. ECF No. 14. Petitioner did not dispute the onset of symptoms in 2016, or that her petition was filed in 2023 (and not sooner than 2019, the statute of limitations deadline), but instead argued that the limitations period should be equitably tolled. Petitioner asserted that she had diligently pursued her rights once she realized the connection between her injuries and the HPV vaccine and became aware of the Vaccine Program. Petitioner also made allegations not relevant to a Vaccine Act claim, about the perfidious conduct of the vaccine manufacturer in fraudulently concealing the HPV vaccine's harmful character from the public. ECF No. 14 at 11. Relatedly, Petitioner argued that the failure of a healthcare professional to

provide her with a Vaccine Information Statement at the time of vaccination can be attributed to the Department of Health and Human Services' failure to systematically ensure that VIS are provided and explained to all vaccine recipients. *Id.* at 2. Petitioner also argued that her minor status when receiving the vaccinations impeded her ability to bring a vaccine claim. *Id.*

Respondent did not file a reply to Petitioner's response.

Legal Standards

The Vaccine Act's statute of limitations is thirty-six months. Sec. 16(a)(2). The statute begins to run from the manifestation of the first objectively cognizable symptom, whether or not that symptom is sufficient for diagnosis (or even recognized by a claimant as significant). *Id.*; *Carson v. Sec'y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013).

The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act's statute of limitations. See Cloer v. Sec'y of Health & Hum. Servs., 654 F.3d 1322, 1340-41 (Fed. Cir. 2011). However, in keeping with applicable U.S. Supreme Court precedent, equitable tolling of a limitations period is to be permitted "sparingly." Irwin v. Dep't of Veterans Affairs, 498 U.S. 89, 96, (1990). The appropriateness of equitable tolling is ultimately to be determined on a case-by-case basis, without rigid application of any relevant overarching guidelines. Holland v. Florida, 560 U.S. 631, 649–50 (2010); accord Arctic Slope Native Ass'n v. Sebelius, 699 F.3d 1289, 1295 (Fed. Cir. 2012).

Petitioners must prove two elements to establish equitable tolling: (1) that petitioner diligently pursued her rights, and (2) an extraordinary circumstance prevented her from timely filing the claim. *K.G. v. Sec'y of Health & Hum. Servs.*, 951 F.3d 1374, 1379 (Fed. Cir. 2020) (citing *Menominee Indian Tribe v. United States*, 577 U.S. 250, 255 (2016)). When first articulating this limited exception to equitable tolling, the Federal Circuit primarily enumerated fraud and duress—but not, for example, *lack of awareness* on a petitioner's part that she might have an actionable claim. *Cloer*, 654 F.3d at 1344–45 (noting that tolling of the Vaccine Act's statute of limitations period is not triggered "due to unawareness of a causal link between an injury and administration of a vaccine").

In *K.G.*, 951 F.3d at 1380–82 (Fed. Cir. 2020), the Circuit more explicitly endorsed the proposition that an individual's demonstrated mental incapacity could be a basis for equitable tolling in the Program. For a mentally incapacitated individual, the Circuit instructed that the details of the individual's relationship with her legal guardian would affect whether there was reasonable diligence or extraordinary circumstances. *K.G.*, 951 F.3d at 1382 (Fed. Cir. 2020). More recently, the Circuit concluded that a parent acting as a legal guardian did not have extraordinary circumstances preventing the filing of a

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petition where the parent: (1) routinely made medical decisions on behalf of the legally incapacitated individual during the relevant time period, (2) had no documented strained relationship with the individual, and (3) had no conflicts of interest dissuading the parent from filing a petition. *W.J. v. Sec'y of Health & Hum. Servs.*, 93 F.4th 1228, 1241 (Fed. Cir. 2024).

<u>Analysis</u>

The untimeliness of this filing is acknowledged by Petitioner, so the only question to be resolved is whether equitable tolling should save the claim. But Petitioner has failed to establish both elements of equitable tolling – diligent pursuit and extraordinary circumstances.

A) Diligent pursuit

Petitioner was a minor when she received the HPV vaccinations in 2016 and 2018. Until she turned eighteen in 2019, Petitioner argues that her diligent pursuit of her vaccine claim was impeded by her minor status when the vaccinations were administered. After turning eighteen, Petitioner argues that she was impeded by the failure of the vaccine administrators to provide her with a VIS or any other information about the Vaccine Program at the vaccination appointments. Petitioner admits that she only learned of the Vaccine Program in 2023 and then began to diligently pursue her vaccine claim.

First, Petitioner incorrectly attempts to leverage her minor status at the time of the vaccinations into an exception to diligent pursuit. The Federal Circuit has conclusively stated that Vaccine Act does <u>not</u> contain a provision for minority tolling and that Congress did <u>not</u> intend to allow minority tolling. *W.J.*, 93 F.4th at 1241. The only savings clause in the Act is for revisions to the Vaccine Injury Table, which allow an otherwise untimely claim for newly added vaccines to be filed. Sec. 16(b). And there is no argument here that a Table claim specifically involving the HPV vaccine was added that would cover Petitioner's delayed filing.²

At best, the Federal Circuit has noted that a guardian's effectiveness in acting on behalf of a legally incapacitated individual should be assessed on a case-by-case basis, and there thus could be circumstances where the adequacy of a guardian's performance of their duties bears on tolling. *K.G.*, 951 F.3d at 1382 (Fed. Cir. 2020). However, Petitioner

of this claim.

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² In fact, the HPV vaccine was added to the Table in 2007 – *nine* years before onset is alleged herein to have occurred. 42 C.F.R. § 100.3 (Vaccine Injury Table); National Vaccine Injury Compensation Program: Addition of Meningococcal and Human Papillomavirus (HPV) Vaccines to the Vaccine Injury Table, 72 Fed. Reg. 19937 (Apr. 20, 2007). The Act's lookback provisions have no relevance at all to the timeliness

has not alleged that her parents or legal guardians were ineffective at managing her medical or legal affairs. I do not find any evidence that Petitioner's parents or legal guardians were ineffective and, thus, I do not find any grounds to toll the statute of limitations while Petitioner was a minor.

Second, turning to Petitioner once she turned eighteen in 2019, the argument about the vaccine administrators' failure to provide a VIS or any other information about the Vaccine Program is wholly unpersuasive. It is beyond question that claims asserted in the Vaccine Program are not subject to a "discovery rule," accruing only when a claimant *learns* he or she might possess a cause of action. Rather, the statute of limitations period is triggered by the onset of Petitioner's symptoms – whether or not onset was understood to be the start of the claimed injurious illness or condition. *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc). And the failure to be advised of the Vaccine Program or the Act does not support equitable tolling of the statute of limitations period for an otherwise-untimely filed petition. *Speights v. Sec'y of Health & Hum. Servs.*, No. 03-2619V, 2013 WL 5944084, at *13 (Fed. Cl. Spec. Mstr. Oct. 17, 2013). Thus, a petitioner cannot generally shield an untimely claim from dismissal by asserting, even in good faith, that she literally was unaware of her Vaccine Act "rights."

B) Extraordinary Circumstances

Petitioner's arguments about the purported fraudulent conduct of the vaccine's manufacturer, in hiding proof of the vaccine's dangers, deserve even less consideration. ECF No. 14 at 11. As a threshold matter, these contentions are speculative and not evidentiarily-supported. And regardless of their actual truth, the fact remains that the Government *has approved* the HPV vaccine for administration to minors, rendering it "covered" under the Act.³ The only issue to be resolved in a Program case is whether (assuming, as here, the claim is not a Table claim) the claim meets the standards for causation – and those standards have nothing to do with a manufacturer's alleged misconduct in preparation or promotion of the underlying vaccine.

These allegations also are not a basis for tolling under the circumstances. Petitioner simply has not shown that contentions of corporate misconduct not specific to, or directed at, her personally could rise to the level of the kind of "fraud" that might excuse failing to file a Program claim in a timely manner. Nor has she persuasively established that the vaccine administrator's "failure to warn," or provide a VIS in 2016 or 2018, is an

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³ The HPV vaccine was first added to the Table in 2007. 42 C.F.R. § 100.3 (Vaccine Injury Table); National Vaccine Injury Compensation Program: Addition of Meningococcal and Human Papillomavirus (HPV) Vaccines to the Vaccine Injury Table, 72 Fed. Reg. 19937 (Apr. 20, 2007).

extraordinary circumstance. Even assuming the factual accuracy of that allegation,⁴ it remains the case (as the Circuit recognized in *Cloer*) that vaccine claims accrue upon onset – and that the failure to be advised of the Vaccine Program does not support equitable tolling. *Cloer*, 654 F.3d at 1340; see also Speights, 2013 WL 5944084, at *13. And arguments about governmental agency knowledge of a failure to warn reflect overheated, almost-conspiratorial allegations that do not come close to excusing the claim's untimely nature.

Conclusion

Thus, Petitioner has failed to establish equitable tolling. This case is dismissed for being untimely filed. The Clerk of Court shall enter judgment accordingly.⁵

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

⁴ As noted above, contrary to Petitioner's claims, the contemporaneous vaccine administration records state that Petitioner and her mother were counseled about the risks of vaccination and provided with VIS at both appointments. Exhibit 18 at 31-37 and 82-87. The only evidence that no VIS or information about the Vaccine Program was provided is Petitioner's affidavit dated December 12, 2023, in which she attested about events that occurred five and seven years earlier, when she was a teenager. Exhibit 12 ¶ 4. Petitioner has not submitted an affidavit from her mother, the only adult present with her at the vaccination appointments.

⁵ If Petitioner wishes to bring a civil action, she must file a notice of election rejecting the judgment pursuant to § 21(a) "not later than 90 days after the date of the court's final judgment."